

Application/Control No. 09/975,621

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REMARKS

This amendment is responsive to the Office Action dated June 4, 2003. Applicant has cancelled claims 23-34, and has added claims 35-80. Claims 35-80 are pending examination on the merits.

Claim Rejection Under 35 U.S.C. § 112

In the Office Action, the Examiner rejected claims 23-34 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. To sum up the Examiner's position, "The claims are full of vague and indefinite language."

Applicants have cancelled claims 23-34 and have added claims 35-80. Applicants submit that claims 35-50 closely reflect cancelled claims 23-34; however said claims stand amended to particularly point out and distinctly claim the subject matter, as required by 35 U.S.C. § 112, second paragraph.

In addition, new claim sets 51-66 and 67-80 essentially repeat the subject matter claimed in claims 23-34 albeit in the form of a computer readable medium for storing instructions for carrying out the methods (claims 51-66) and means-plus-function type apparatus claims (claims 67-80 - but not including claims corresponding to claims 32-33 or 48-49), respectively.

Applicants respectfully assert that new claims 51-66 are expressly and inherently supported by the application as originally filed as evidenced throughout the application (e.g., the background at page 3, lines 7-15) and as such microprocessor based, programmable devices coupled to storage media are well known and used in the art.

Since the presently-pending three claim sets are closely related to the originally submitted claims, Applicants respectfully assert that the following remarks and arguments apply equally to each of the pending claims.

Claim Rejection Under 35 U.S.C. § 102

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In the Office Action, the Examiner rejected claims 23 and 24 under 35 U.S.C. § 102(e) as being anticipated by U.S. Pat. No. 5,908,392 issued to Wilson et al. ("Wilson"). According to the Examiner, Wilson's trigger signal is inherently out of range and Wilson further discloses overwriting of previously recorded data in a snapshot buffer.

Applicants respectfully traverse the rejections as enumerated hereinbelow.

Applicants have cancelled claims 23 and 24, rendering the rejections moot. However, the Applicants have also added claims 35-80, which recite many of the same elements as set forth in the cancelled claims. It should be noted, however, that claims 35-80 do not represent a narrowing of claimed subject matter, but a broadening of claimed subject matter. In particular, elements that had been recited as part of now-cancelled independent claims 23 and 29 have now been moved into dependent claims. Pertinent to the rejection of claims 23 and 24, the claim element pertaining to detection of out-of-range values has been moved to dependent claim 36 (as well as 52 and 68) and do not form a part of independent claim 35 (51 or 67).

Even though pending independent claim 35 is broader than now-cancelled independent claims 23 and 29, Wilson still does not anticipate claim 35. "A single prior art reference anticipates a patent claim if it expressly or inherently describes each and every limitation set forth in the patent claim." Trintec Indus. Inc. v. Top-U.S.A. Corp., 63 USPQ2d 1597, 1599 (Fed. Cir. 2002). "Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." Id.

Claim 35 recites monitoring an electrogram signal to find a trigger event in the electrogram signal, generating a trigger indicator signal upon finding the trigger event, recording a plurality of sampled values of the electrogram signal in memory, and recording the trigger indicator signal in memory contemporaneously with the recording of the sampled electrogram signal.

Claim 35 also recites that recording the trigger indicator signal in memory comprises replacing one of the sampled values with the trigger indicator signal. (Now-cancelled claim 23 included a similar element, i.e., "recording trigger detected signal in an ECG data record memory by replacing one sampled value of the ECG data record

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with said trigger signal.") Wilson fails to teach or suggest the memory management technique recited in claim 35. In particular, Wilson does not disclose replacing any electrogram (or ECG) data with a trigger indicator signal. Accordingly, Wilson does not anticipate claim 35, nor does Wilson anticipate claim 36, which depends on claim 35.

Claim 38 recites the method according to claim 35, wherein the trigger event comprises detection of out-of-range values of the electrogram signal. According to the Examiner, Wilson's trigger signal is inherently out of range of the electrogram/ECG data because the trigger signal and the electrogram/ECG data are not the same type of data. As recited in claim 36, "out-of-range" does not pertain to whether electrogram data and trigger signal data are of the same type. Rather, claim 36 recites "out-of-range values of the electrogram signal" and does not mention the trigger signal at all. Detection of out-of-range values of the electrogram signal is one kind of trigger event.

In view of the differences identified above, Wilson clearly fails to anticipate the features set forth in claims 35 and 36 (and features set forth in the claims corresponding to claims 35 and 46; namely, claims 51,52 and 67,68).

Claim Rejections Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 25-30 and 32-34 under 35 U.S.C. § 103(a) as being unpatentable over Wilson. According to the Examiner, Wilson discloses the claimed invention except for compression of signals as recited in now-cancelled claim 25, recording of noise trigger signals as recited in now-cancelled independent claim 29, and parsing and displaying of icons as recited in now-cancelled claims 26-28 and 32-34. The Examiner concluded, however, that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the recording and storage system as taught by Wilson, to include those elements. According to the Examiner, it was known in the art that recording and storage systems use compression to increase the amount of data that can be recorded, that recording noise trigger signals can be used to determine whether ECG data may be invalid, and that parsing and displaying help the physician determine whether the system is

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operating correctly or whether the arrhythmias may have started or whether the ECG signal is invalid due to noise.

Before addressing questions under 35 U.S.C. § 103, Applicants note that independent claim 35 is allowable in light of Wilson for the reasons given above. Claims 36-50 depend, directly or indirectly, upon claim 35, and are therefore allowable as well. Likewise, claims 52-66 depend, directly or indirectly, upon claim 51 and are also allowable. Furthermore, claims 68-80 depend, directly or indirectly, upon claim 67 and are therefore also presently allowable.

Applicants also note, although claims 25-30 and 32-34 have been cancelled and rejection of those claims has been rendered moot, claim elements pertaining to compression, noise trigger/indicator signals, parsing and displaying of icons are recited in new claims 38-46.

In connection with combining references to support an assertion of obviousness, it is well established that the Examiner bears the burden of establishing a prima facie case of obviousness: In re Oetiker, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). In doing so, the Examiner must determine whether the prior art provides a "teaching or suggestion to one of ordinary skill in the art to make the changes that would produce" the claimed invention. In re Chu, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995). A prima facie case of obviousness is established only when this burden is met.

The burden is still on the Examiner even when the Examiner relies upon a single reference. "Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference." In re Kotzab, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000).

In the case of In re Lee, 61 USPQ2d 1430 (Fed. Cir. 2002), the Federal Circuit stated: "This factual question of motivation is material to patentability, and [can] not be resolved on subjective belief and unknown authority." *Id.* at 1434. Determination of patentability must be based on evidence, *id.* at 1434, and the Examiner provided none: no references pertaining to aggregation or averaging were cited, no official notice was taken, no evidence of any kind was presented. The Examiner's failure to present an evidentiary basis for the decision is clearly a legal error. *Id.* Assertions such as "common knowledge and common sense," even if assumed to derive from the

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Examiner's expertise, are not evidence, and conclusory statements do not fulfill the Examiner's obligation to make an evidentiary record. Id. at 1434-35; In re Dembiczak, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

If indeed the elements were known in the art, then the Examiner ought to present evidence to support that conclusion. In re Lee, 61 USPQ2d at 1435 ("[W]hen they rely on what they assert to be general knowledge to negate patentability, that knowledge must be articulated and placed on the record."). The failure to do so renders the Examiner's rejection arbitrary, capricious and unreasonable. See id. at 1434. The Examiner may not arbitrarily, capriciously and unreasonably deny a claim by a mere declaration of obviousness without a supporting evidentiary record.

The Examiner presented no evidence of any suggestion or motivation to modify the Wilson techniques to arrive at the claimed invention. Nor has the Examiner presented any evidence that the recited elements are known in the art. The record consists exclusively of conclusory statements by the Examiner, which are not evidence and which cannot support rejections under 35 U.S.C. § 103.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 38-46 (and 54-52 and 70-78) under 35 U.S.C. § 103(a). Withdrawal of this ground of rejection is hereby earnestly and respectfully requested.

Allowable Subject Matter

The Examiner rejected now-cancelled claim 31 under 35 U.S.C. § 112, second paragraph, but did not reject claim 31 under 35 U.S.C. § 102 or 35 U.S.C. § 103. Now-cancelled claim 31 recited "other sensor data in which said ECG in memory at a rate of up to one sensor data value for 30 ECG data values." Although claim 31 has been cancelled, claim 48 recites "the method further comprising recording one sample of other sensor data per thirty sampled values of the electrogram signal." Applicants submit that if now-cancelled claim 31 is allowable in light of Wilson, new claim 48 is allowable. For the same reason, Applicants assert that claim 64 and claim 70 be deemed allowable in view of Wilson.

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Elements recited in the cancelled claims corresponding to new claims 37, 47 and 49-50 were not specifically addressed by the Examiner in the Office Action. Applicants submit that claims 37, 47 and 49-50 are allowable as presented herein.

The Examiner remarked that claims rejected under 35 U.S.C. § 112, second paragraph, would be allowable if the Examiner's suggested claim format were to be followed. The Examiner also declared, however, that the corrected claims may still be subject to rejection under 35 U.S.C. § 102 or 35 U.S.C. § 103. New claims 35-50 correct the problems under 35 U.S.C. § 112, second paragraph. For the reasons given above, claims 35-50 are neither anticipated by Wilson nor obvious in light of Wilson, and are therefore allowable.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 13-2546. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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4 Sept. 03

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